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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,708	08/31/2001	Richard B. Thompson	3645-0104P	9931

2292 7590 11/05/2003

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,708

Applicant(s)

THOMPSON ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4,6-12 and 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-24 are pending

Restriction/Election

2. Examiner is regrouping Claim 8 from Group III drawn to a composition comprising a mixture of an apo-carbonic anhydrase with photo-luminescent compounds, wherein said anhydrase is not conjugated with said photo-luminescent compounds to Group I, a composition comprising an apo-carbonic anhydrase protein conjugated to photo-luminescent compounds.
3. Applicants' election with traverse of Group III, Claims 2, 5, 8 and 13 and the species of 7-fluoro-benz-2-oxa-1, 3-diazole-4-sulfonamide: β -mercaptoethanol adduct filed August 22, 2003 to Office Action dated July 18, 2003 is acknowledged and entered. Applicants' traversal is on the ground (s) that Examiner's restriction requirement is incorrect and at least the claims encompassed in Groups I, II and IV should be examined together and the Claims of groups III and V should be examined together because examining all the pending claims together in the instant application will not be burdensome to the Examiner, especially because some of the claims have been amended.

Applicants' arguments have been carefully considered, but are not found persuasive because of the reasons of record on pages 2-4 in Office Action dated July 18, 2003 as paper number 7 and for additional reasons as discussed below:

Amended Claim 14 is drawn to a subject matter that still comprises components other than those that are encompassed in invention in Group I, Claims 1, 3-4 and 6-12. Furthermore, the claims encompassed in Group I are drawn strictly to a composition comprising apo-carbonic anhydrase protein conjugated to photo-luminescent compounds, whereas the kit claimed in Claim 14 encompasses both conjugated and non-conjugated photo-luminescent compounds in addition to other components that constitute said kit. For the same reason, Claims encompassed in invention of Group III are not unitary with the claims constituting Group V, because the kit claimed in Group V requires constituents other than those encompassed in Group III. Additionally, the search for each of the distinct inventions of Groups I-V is not co-extensive

particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. The restriction requirement is, therefore, still deemed proper and is made FINAL.

Accordingly, Claims 1, 3-4, 7-12 and 14-24 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited above be canceled in response to this Office action to expedite prosecution.

4. Claims 2, 5 and 13 are examined on merits insofar as they read on the elected species.

Information Disclosure Statement

5. The information disclosure statement filed 04/06/2001 (Paper Number 5) has been received and considered.

Priority

6. Applicants' claim for domestic priority under 35 U.S.C. §§ 119 (e) and 120 is acknowledged.

Claim Objections

7. Claims 2, 5 and 13 are objected to because of the following informalities: The terminology "7-fluorobenz-2-oxa-1, 3-diazole-4-sulfonamide:β-mercaptoethanol adduct" is objected to because it is a known compound with CAS Registry number, 91366-67-5, and is referred to as "4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole". Product by process type language should not be used.

Appropriate correction is required.

Specification

8. The abstract of the disclosure is objected to because it contains more than 150 words.

Correction is required. See MPEP § 608.01(b).

Claim Rejections – 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 2 and 5 are rejected under 35 U.S.C. §102(e) as anticipated by Thompson et al. (U.S. Patent 5,545,517).

Thompson et al. teach a composition comprising a bovine erythrocyte carbonic anhydrase protein converted to apo configuration by stripping zinc from said carbonic anhydrase and mixing said zinc stripped bovine erythrocyte carbonic anhydrase with dansylamide. Dansylamide is a photo luminescent compound because it produces blue fluorescence when mixed with apo-carbonic anhydrase from bovine erythrocytes (Column 8, Lines 34-63). Thompson et al. further describe a human apo-carbonic anhydrase (Column 6, Lines 1-7) and an analyte medium comprising a photoluminescent indicator species mixed with a complex comprising apo-carbonic anhydrase and a metal ion (Column 6, Lines 43 to Column 7, Line 11, Figure 5).

Therefore, the reference anticipates claims 2 and 5.

11. Claim 5 is rejected under 35 U.S.C. §102(b) as anticipated by Thompson et al (Journal of Fluorescence, 1992, 5, Pages 123-130).

Thompson et al. teach a composition comprising a human carbonic anhydrase protein converted to apo configuration by stripping zinc from said carbonic anhydrase and mixing said zinc stripped apo-carbonic anhydrase with dansylamide (Page 127, Column 2, Lines 8-24 and 39-41) to measure zinc concentration.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. § 103

12. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

14. Claims 2, 5 and 13 are rejected under 35 U.S.C. § 103 (a) as obvious over Thompson et al. (U.S. Patent 5,545,517) and Thompson et al. (Journal of Fluorescence, 1992, 5, Pages 123-130) in view of Toyo'oka et al. (New Fluorogenic Reagent having halogenbenzofurazan structure for Thiols. 1984. Anal. Chem., 56, Pages 2461-2464).

Teachings from Thompson et al. (U.S. Patent 5,545,517) and Thompson et al. (Journal of Fluorescence, 1992, 5, Pages 123-130) have been discussed *supra*. Cited prior art references teach a composition comprising an apo-carbonic anhydrase protein and a photoluminescent molecule (i.e., dansylamide). They, however, do not teach the photoluminescent molecule to be 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole.

Toyo'oka et al. teach that reacting ABD-F with mercaptoethanol yields the fluorophore, 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole, (Table III) with a relative fluorescence in excess of the parent compound ABD-F (RFI = 122).

A person of ordinary skill in the art at the time the invention was made would have been motivated to substitute the fluorophore, 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole, of Toyo'oka et al. for the fluorophores in the compositions of Thompson et al.

(U.S. Patent 5,545,517) and Thompson et al. (1992) because Toyo'oka et al. establish that their fluorophore has a particularly strong RFI, good stability, and has low fluorescence background making it very suitable for fluorescence studies.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine teachings from Thompson et al. (US 5,545,517), Thompson et al. (1992) and Toyo'oka et al. to obtain a composition comprising a mixture of (human) apocarbonic anhydrase and 4-(2-Hydroxyethylthio)-7-aminosulfonyl-2, 1, 3-benzoxadiazole.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.


Conclusion

15. No Claims are allowed.

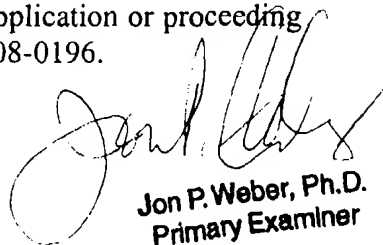
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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November 3, 2003


Jon P. Weber, Ph.D.
Primary Examiner